SAFETY NOTE 24 IDENTIFYING BE-ASSOCIATED WORKERS WITH PREVIOUS POTENTIAL EXPOSURE

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INTRODUCTION

DOE's Chronic Beryllium Disease (CBD) rule, 10 CFR 850, requires that training be provided (850.37(a)(1)) and that medical surveillance be offered (850.24(a)(1)) to all *beryllium-associated workers*. The definition of *beryllium-associated worker* includes... a current worker whose work history shows that the worker may have been exposed to airborne concentrations of beryllium at a DOE facility (850.3(a)). No quantitative threshold is provided. This fact is understandable given the uncertainties in the associated dose-response relationship. Nonetheless, a practical numerical threshold is essential for the effective and efficient implementation of the rule.

The particular problem with designating beryllium-associated workers at Fermilab is the relatively large number of people, perhaps hundreds, who have had negligible exposures to beryllium, i.e., brief durations and low concentrations. Most of these (potential) exposures result from suspension of dust during bulk handling of beryllium items or from walking by beryllium storage areas. Lifetime exposure durations fall in the range of minutes to days. The most common air sampling result for both personal and area monitoring has been *none detected*: typically <0.1 $\mu g/m^3$. One must question whether such individuals are truly at risk of developing CBD. For example, no cases of Be-related disease have been identified in Fermilab's ~30 year history. In fact, Fermilab has not experienced any chronic lung disease cases of any kind.

Fermilab is committed to protecting the health of its workers as well as complying with applicable requirements. However, it is also desirable to approach these goals in ways that are both effective and cost efficient. Unfortunately, the cost of complying with beryllium-associated worker requirements can be rather high: initial costs ~\$400 per person¹. Though purposely vague and suggestive of high toxicity, DOE's CBD rule allows employers to define what is meant by the phrase ...may have been exposed to airborne concentrations of beryllium...

This document reviews pertinent information on beryllium toxicity and describes the development of threshold exposure criteria for including current workers with

¹ Direct costs are ~\$300 per person for lymphocycte proliferation testing (LPT) and B-reader chest radiographs. Indirect costs are ~\$100 per person assuming that four hours of productivity are lost to participate in testing and training.

previous potential beryllium exposure in Fermilab's Chronic Beryllium Disease Prevention Program.

LITERATURE REVIEW

It seems reasonably clear that there is a threshold for CBD and this threshold lies between 0.01 and 0.1 µg/m³. The U.S. average concentration of beryllium in outdoor air is 0.03 ng/m³, though in cities it is 0.2 ng/m³ (ATSDR 1992). Since CBD does not occur in the general population, the threshold must lie somewhere above these concentrations. Eisenbud, et al (1949) identified 10 cases of CBD in 10,000 members of the public within a two-mile radius of a beryllium plant located near Lorain, OH. The disease was diagnosed via radiography and concentrations were estimated to lie between 0.01 and 0.1 µg/m³, with most cases occurring nearer the 0.1 ug/m³ level. Although the diagnostic technique was fairly insensitive by today's standards, exposures occurred round-the-clock for seven years. Yoshida, et al (1997) found an occupational threshold of 0.01 μg/m³ (TWA) for promotion of a cell-mediated immune response in workers at beryllium-copper alloy manufacturing factories. A positive response was defined as any statistically significant increase in BeLPT. It should be noted that this was typically less than the minimal response used to define "sensitization." However, air samples were collected via area monitors: a technique that often underestimates actual exposures to individuals.

The EPA's ambient concentration limit for beryllium in the vicinity of a stationary source is $0.01 \,\mu\text{g/m}^3$, averaged over a 30-day period. This 30-day average is the only limit, i.e., no shorter term restriction is defined.

The EPA's inhalation reference concentration (RfC) for beryllium is $0.02~\mu g/m^3$ (1998). The RfC is an estimate of the continuous inhalation exposure to the human population, including sensitive subgroups, that is likely to be without an appreciable risk of deleterious effects during a lifetime. This estimate is assumed to be correct to within an order of magnitude. The critical effect in this case is beryllium sensitization and progression to CBD.

Wambach and Tuggle (2000) recommended an 8-hour TWA of 0.1 $\mu g/m^3$ based on an application of current standard-setting principles including a review of available epidemiologic data.

DOE's CBD rule has an action level of $0.2 \,\mu g/m^3$, calculated as an 8-hour TWA. Where exposures exceed this level, controls must be implemented (other than medical surveillance and training). The permissible exposure limit is the same as that established in 29CFR1910.1000: $2 \,\mu g/m^3$ as an 8-hour TWA, $5 \,\mu g/m^3$ as a ceiling (averaged over any 15 minute period), and $25 \,\mu g/m^3$ as a 30-minute peak (never > than this for a cumulative 30-minute period) per 8-hour shift.

The preceding information is summarized in the table below.

Conc (mg/m³)	Endpoint	Modifiers regarding occupational exposure	Reference
0.00003 - 0.0002	Ambient air concentration in US. No CBD.	Below threshold ↑	ATSDR (1992)
0.01	Significant increase in BeLPT	Sensitive endpoint ↑ Area monitoring ↑	Yoshida, et al (1997)
0.01	EPA ambient air limit	Round-the-clock exposure ↑ Includes sensitive population ↑	40CFR61.32
0.02	RfC	Round-the-clock exposure ↑ Includes sensitive population ↑	EPA (1998)
0.01 - 0.1	10/10,000 CBD cases	Insensitive endpoint ↓ Cases toward high end ↑ Round-the-clock exposure ↑ Includes sensitive population ↑	Eisenbud, et al (1949)
0.1	Proposed TWA exposure limit	OK?	Wambach and Tuggle (2000)
0.2	DOE TWA action level	OK?	10CFR850
2	DOE TWA exposure limit	N/A	10CFR850
5	DOE ceiling exposure limit	N/A	10CFR850
25	DOE peak exposure limit	N/A	10CFR850

ANALYSIS

A review of published information suggests that the threshold for beryllium sensitization in an occupational setting is greater than 0.01 μ g/m³. Though this clearly holds for longer-term exposures (~years), the threshold for shorter-term exposures (~days) is less clear. However, authors tend to use an inverse concentration-time relationship to explain the manner in which anecdotally exposed personnel contract CBD, i.e., ...it was likely due to a brief but high concentration exposure... In the absence of data, a linear dose-response is often assumed. For example, Wambach and Tuggle (2000) employed this approach in their derivation of an updated exposure limit for beryllium. This linear relationship is also assumed in the EPA's ambient air limit for beryllium that is averaged over a 30-day period. These two examples are utilized here to derive criteria for including workers in Fermilab's CBDPP.

The EPA allows a cumulative exposure (?X) of 7.2 μ g-hr/m³ over a 30-day calendar period, *viz*.:

$$\int_{\lim it} X = 0.01 \frac{\mathbf{m} g}{m^3} * 30 calendar days * \frac{24 hours}{calendar day} = 7.2 \frac{\mathbf{m} g - hour}{m^3}$$

Since this cumulative exposure is permitted for outdoor air, its application to workroom air is reasonable. Therefore, workers should be included in the program if they ever experienced a cumulative exposure exceeding 7.2 μ g-hr/m³ over any 30-day calendar period. This approach works well down to exposures

of 36 hours. Below that, the DOE TWA action level of 0.2 $\mu g/m^3$ would be exceeded.

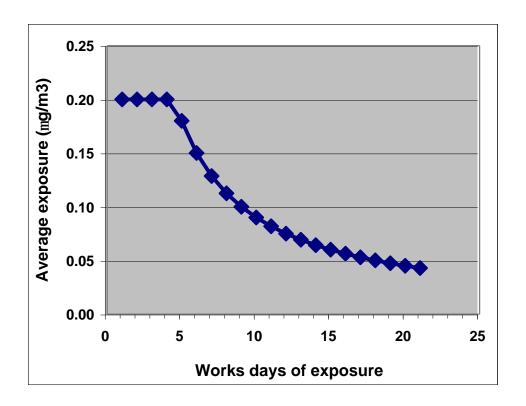
Therefore, the threshold exposure criteria for including present workers with previous potential beryllium exposure in Fermilab's CBDPP is summarized below. Workers should be included if either value is exceeded.

Threshold exposure criteria

Description	Numerical limit	Time constraints
DOE action level (AL)	0.2 μg/m ³	8-hour TWA
EPA ambient air limit (AAL)	7.2 μg-hr/m ³	30 calendar days

Below are tabulated values that can be used to determine whether a worker should be included in the program. Note that there are only ~21 work days in 30 calendar days. [Actually, most workers would have fewer than 21 days due to holidays, vacation days, and sick days.]

Work days	Work hours	Average exposure over period (mg/m3)	Criterion
1	8	0.2	DOE AL
2	16	0.2	DOE AL
3	24	0.2	DOE AL
4	32	0.2	DOE AL
5	40	0.180	EPA AAL
6	48	0.150	EPA AAL
7	56	0.129	EPA AAL
8	64	0.113	EPA AAL
9	72	0.100	EPA AAL
10	80	0.090	EPA AAL
11	88	0.082	EPA AAL
12	96	0.075	EPA AAL
13	104	0.069	EPA AAL
14	112	0.064	EPA AAL
15	120	0.060	EPA AAL
16	128	0.056	EPA AAL
17	136	0.053	EPA AAL
18	144	0.050	EPA AAL
19	152	0.047	EPA AAL
20	160	0.045	EPA AAL
21	168	0.043	EPA AAL



REFERENCES

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EPA. 40 CFR 61.32 Emission standard. Subpart C-national emission standard for beryllium.

EXCERPTS FROM 10 CFR 850 DOE'S CHRONIC BERYLLIUM DISEASE PREVENTION PROGRAM http://tis-nt.eh.doe.gov/be/berule.pdf

10 CFR 850.3(a) Definitions.

Beryllium-associated worker means a current worker who is or was exposure or potentially exposed to airborne concentrations of beryllium at a DOE facility, including:...

(2) A current worker whose work history shows that the worker may have been exposed to airborne concentrations of beryllium at a DOE facility...

10CFR850.22 Permissable exposure limit.

The responsible employer must assure that no worker is exposed to an airborne concentration of beryllium greater that the permissible exposure limit established in 29CFR1910.1000, as measured in the worker's breathing zone by personal monitoring...

10 CFR 850.23 Action level.

- (a) The responsible employer must include in its CBDPP an action level that is no greater that $0.2 \,\mu\text{g/m}^3$, calculated as an 8-hour TWA exposure, as measured in the worker's breathing zone by personal monitoring.
- (b) If an airborne concentration of beryllium is at or above the action level, the responsible employer must implement 850.24(c) (periodic monitoring), 850.25 (exposure reduction and minimization), 850.26 (regulated areas), 850.27 (hygiene facilities and practices), 850.28 (respiratory protection), 850.29 (protective clothing and equipment), and 850.38 (warning signs) of this part.

10 CFR 850.24 Medical surveillance.

(a) General. (1) The responsible employer must establish and implement a medical surveillance program for beryllium-associated workers who voluntarily participate in the program...

10 CFR 850.37 Training and counseling.

- (a) The responsible employer must develop and implement a beryllium training program and ensure participation for:
 - (1) Beryllium-associated workers;...